UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MARY TOMASELLI and EUGENE TOMASELLI,

Plaintiffs,

v.

ZIMMER, INC., ZIMMER HOLDINGS, INC., and PIONEER SURGICAL TECHNOLOGY, INC.,

Defendants.

No. 14-CV-4474 (RA)

OPINION AND ORDER ADOPTING REPORT AND RECOMMENDATION

RONNIE ABRAMS, United States District Judge:

Plaintiffs Mary Tomaselli and Eugene Tomaselli bring this products liability action against Defendants Pioneer Surgical Technology, Inc., Zimmer, Inc., and Zimmer Holdings, Inc., alleging injuries arising from the use of a Greater Trochanter Reattachment ("GTR") device to repair a fracture in Ms. Tomaselli's right greater trochanter. Before the Court is the January 20, 2017 Report and Recommendation of the Hon. Sarah Netburn, United States Magistrate Judge, recommending that the Court grant Defendants' motion for summary judgment and deny Plaintiffs' cross-motion for summary judgment. For the reasons set forth below, the Court adopts this recommendation.

BACKGROUND[1]

In 2010, Ms. Tomaselli fractured her right greater trochanter, a part of the femur bone near the hip. *See* Decl. of Judi Abbott Curry in Supp. of Mot. for Summ. J. ("Curry Decl.") Ex. F (Dkt. 106-6). Over the next several months, Ms. Tomaselli experienced continuous pain, struggled to

[1] The Court assumes familiarity with the facts underlying this case, *see* Report at 1–6, and recites only those facts relevant to Plaintiffs' objections.

walk long distances, and demonstrated weakness and balance deficits while standing. *See* Curry Decl. Ex. C ("Tomaselli Dep. Tr.") at 45:4–12, 45:21–46:2 (Dkt. 106-3); Curry Decl. Ex. H (Dkt. 106-8); Curry Decl. Ex. J (Dkt. 106-10). On January 19, 2011, Ms. Tomaselli met with Dr. Ohannes Nercessian, an orthopedic surgeon at New York Presbyterian Hospital, who determined that her fracture had not fully healed and advised her that surgery would be necessary if she hoped to walk without a cane. *See* Curry Decl. Ex. J. Dr. Nercessian explained to Ms. Tomaselli that this surgery would involve the implantation of a "greater trochanteric claw plate with cables," and that possible complications include "slight pain over where the plate is." *Id.*; *see also* Tomaselli Dep. Tr. at 50:14–19. Dr. Nercessian did not advise Ms. Tomaselli of any risk that the cables in this device could break. *See* Curry Decl. Ex. D ("Nercessian Dep. Tr.") at 37:6–8, 37:19–22 (Dkt. 106-4).

On February 1, 2011, Dr. Nercessian surgically implanted a GTR device, manufactured by Pioneer Surgical and distributed by Zimmer, in Ms. Tomaselli's right greater trochanter. *See* Curry Decl. Ex. K (Dkt. 106-11), Ex. S at 19 (Dkt. 106-19). The GTR device includes a "claw and cable": the "claw" is a metal plate placed upon the greater trochanter, while the cable is a set of two metal wires that affix the plate to the bone. *See* Nercessian Dep. Tr. at 45:11–20, 47:9–13; Curry Decl. Ex. R (Dkt. 106-18). The label of the GTR device provided instructions for use ("IFU"), which identified "possible adverse effects," including "[f]raying, kinking, loosening, or breakage of the cables securing the device." Curry Decl. Ex. W (Dkt. 106-23). Dr. Nercessian did not read the IFU prior to operating on Ms. Tomaselli. *See* Nercessian Dep. Tr. at 71:13–18.

On April 27, 2012, after Ms. Tomaselli reported experiencing pain in her pelvic region and thigh, an x-ray revealed that one of the cables in the GTR device had broken. *See* Curry Decl. Ex. O (Dkt. 106-15). The cable had "unwound itself" and lay longitudinally along Ms. Tomaselli's

femur. *Id.* Dr. Nercessian testified that he had never seen cable breakage in a GTR device prior to his work with Ms. Tomaselli. *See, e.g.*, Nercessian Dep. Tr. at 85:22–23. Based on his experience, however, Dr. Nercessian testified that cable breakage is "a known risk of any wire, any cable," *id.* at 102:11, and that cables tend to break "[b]y reaching and exceeding the maximum fatigue strength of the metal," *id.* at 91:15–16. Asked whether a cable implanted to repair a greater trochanter fracture may break if the fracture fails to fully heal—a so-called "nonunion"—Dr. Nercessian replied, "Definitely." *Id.* at 91:17–19. Dr. Nercessian did not recommend removing the GTR device, which remains implanted in Ms. Tomaselli. *See* Curry Decl. Ex. B. ¶ 4 (Dkt. 106-2); Nercessian Dep. Tr. at 98:16–25.

On April 25, 2014, Plaintiffs filed a complaint against Defendants in New York state court, asserting claims of negligence, strict products liability, breach of the implied warranty of merchantability, breach of the implied warranty of fitness for purposes intended, and breach of express warranties. *See* Curry Decl. Ex. A (Dkt. 106-1).[2] On June 20, 2014, Defendants removed the action to this Court. Dkt. 2. On March 23, 2015, the Court denied Plaintiffs' motion to remand and dismissed Plaintiffs' claims against Columbia University Medical Center, the New York and Presbyterian Hospital, and the Trustees of Columbia University in the City of New York. Dkt. 41. On June 13, 2016, the remaining Defendants moved for summary judgment. Dkt. 103. On July 22, 2016, Plaintiffs filed an opposition to Defendants' motion and a cross-motion for summary judgment. Dkts. 113, 118. On January 20, 2017, Judge Netburn issued the Report, which recommended that the Court grant Defendants' motion for summary judgment and deny Plaintiffs' cross-motion for summary judgment. Dkt. 131. On February 2, 2017, Plaintiffs filed objections to the

[2] In addition, Mr. Tomaselli asserted a claim for loss of consortium. *See* Curry Decl. Ex. A.

Report and Recommendation, *see* Pls.' Objs. (Dkt. 132), to which Defendants responded on February 16, 2017, *see* Defs.' Resp. to Pls.' Objs. (Dkt. 133).

LEGAL STANDARDS

A. Standard of Review

A district court "may accept, reject, or modify, in whole or in part, the findings or recommendations made by the magistrate judge." 28 U.S.C. § 636(b)(1). Under Federal Rule of Civil Procedure 72(b), a party may make "specific written objections to the proposed findings and recommendations" within fourteen days of being served with a copy of a magistrate judge's recommended disposition. Fed. R. Civ. P. 72(b)(2). A district court must review de novo "those portions of the report or specified proposed findings or recommendations to which objection is made." 28 U.S.C. § 636(b)(1). "However, when the objections simply reiterate previous arguments or make only conclusory statements, the Court should review the report for clear error." *Brown v. Colvin*, 73 F. Supp. 3d 193, 197 (S.D.N.Y. 2014). "To accept those portions of the report to which no timely objection has been made, 'a district court need only satisfy itself that there is no clear error on the face of the record.'" *Hunter v. Lee*, No. 13-CV-5880 (PAE), 2016 WL 5942311, at *1 (S.D.N.Y. Oct. 11, 2016) (quoting *King v. Greiner*, No. 02-CV-5810 (DLC), 2009 WL 2001439, at *4 (S.D.N.Y. July 8, 2009)).

B. Summary Judgment

To prevail on a motion for summary judgment, the movant must show "that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "An issue of fact is genuine and material if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Cross Commerce Media, Inc. v. Collective, Inc.*, 841 F.3d 155, 162 (2d Cir. 2016). "The movant bears the burden of demonstrating

the absence of a question of material fact." *Chaparro v. Kowalchyn*, No. 15-CV-1996 (PAE), 2017 WL 666113, at *3 (S.D.N.Y. Feb. 17, 2017). "When a motion for summary judgment is properly supported by documents or other evidentiary materials, the party opposing summary judgment may not merely rest on the allegations or denials of his pleading; rather his response, by affidavits or otherwise as provided in the Rule, must set forth 'specific facts' demonstrating that there is 'a genuine issue for trial.'" *Wright v. Goord*, 554 F.3d 255, 266 (2d Cir. 2009) (quoting Fed. R. Civ. P. 56(e)); *see also Celotex Corp. v. Catrett,* 477 U.S. 317, 323 (1986). In determining whether to grant summary judgment, the Court must "construe the evidence in the light most favorable to the non-moving party and draw[] all reasonable inferences in its favor." *Mitchell v. City of N.Y.*, 841 F.3d 72, 77 (2d Cir. 2016) (quoting *Costello v. City of Burlington*, 632 F.3d 41, 45 (2d Cir. 2011)).

DISCUSSION

Plaintiffs object only to the Report's recommendation to grant summary judgment to Defendants on their failure-to-warn claim. *See* Pls.' Objs. at 2–6; Report at 7–11. Defendants argue that the Court should review this objection for clear error. *See* Defs.' Resp. to Pls.' Objs. at 1–2. The Court need not decide whether clear error or de novo review is appropriate, however, because it finds no error, clear or otherwise, in the Report's determination that Defendants are entitled to summary judgment on Plaintiffs' failure-to-warn claim.

To prevail on a failure-to-warn claim against a manufacturer of a drug or medical device, a plaintiff must demonstrate that (1) the warning was inadequate, and (2) the failure to adequately warn was a proximate cause of his or her injuries. *See Figueroa v. Boston Sci. Corp.*, 254 F. Supp. 2d 361, 369–70 (S.D.N.Y. 2003); *see also, e.g.*, *Ohuche v. Merck & Co.*, 903 F. Supp. 2d 143, 149 (S.D.N.Y. 2012); *Glucksman v. Halsey Drug Co.*, 553 N.Y.S.2d 724, 726 (1st Dep't 1990). "The

manufacturer's duty is to warn of all potential dangers . . . that it knew, or, in the exercise of reasonable care, should have known to exist." *Martin v. Hacker*, 628 N.E.2d 1308, 1311 (N.Y. 1993). A warning is adequate as a matter of law if it provides "specific detailed information on the risks" of the drug or medical device. *Id.* at 1312; *see also McDowell v. Eli Lilly & Co.*, 58 F. Supp. 3d 391, 403 (S.D.N.Y. 2014); *Sita v. Danek Med., Inc.*, 43 F. Supp. 2d 245, 259 (E.D.N.Y. 1999). "To constitute proximate cause, an inadequate warning must be a *substantial cause* of the events leading to the injury." *Figueroa*, 254 F. Supp. 2d at 370 (emphasis in original) (citation omitted).

Under New York law, "product warnings are intended for the physician, 'whose duty it is to balance the risks against the benefits of various treatments and to prescribe the treatments he or she thinks best.'" *Prohaska v. Sofamor, S.N.C.*, 138 F. Supp. 2d 422, 444 (W.D.N.Y. 2001) (quoting *Sita*, 43 F. Supp. 2d at 259); *see also Martin*, 628 N.E.2d at 1311. Under the "informed intermediary" doctrine, a manufacturer "discharges its duty by providing the physician with sufficient information concerning the risks of the device." *Sita*, 43 F. Supp. 2d at 259; *see also Martin*, 628 N.E.2d at 1311. Moreover, "'where the treating physician is independently aware' of potential adverse events, that knowledge is 'an intervening event relieving the manufacturer of any liability to a patient under the failure to warn theory.'" *McDowell*, 58 F. Supp. 3d at 406 (quoting *Banker v. Hoehn*, 718 N.Y.S.2d 438, 440–41 (3d Dep't 2000)). "A physician's existing awareness of a potential risk or side effect thus 'severs the causal chain' between an allegedly inadequate warning and a plaintiff's injury." *Id.* (alterations omitted) (quoting *Glucksman*, 553 N.Y.S.2d at 726); *see also, e.g.*, *Figueroa*, 254 F. Supp. 2d at 370 (explaining that the chain of proximate causation in failure-to-warn cases is broken "if a treating physician is well aware of the risks of a medical device, independent of any warning by the manufacturer").

Plaintiffs argue that summary judgment on their failure-to-warn claim is not appropriate because both the adequacy of Defendants' warnings and proximate cause are genuinely disputed. The Court need not address the adequacy of Defendants' warnings, however, because any inadequacy in the warnings of the GTR device did not proximately cause Plaintiffs' injuries.

Under the informed intermediary doctrine, Defendants may not be found liable to Plaintiffs on a failure-to-warn theory because there is no genuine dispute that Dr. Nercessian was independently aware of the risk of cable breakage in the GTR device. As an initial matter, there is no dispute that Dr. Nercessian is an "informed intermediary": he testified that he has completed residencies and fellowships in orthopedic surgery at several institutions, obtained board certification in orthopedic surgery three times, and performed over five thousand hip surgeries during his thirty-year career. *See* Nercessian Dep. Tr. at 9:3–10:15, 10:20–11:2, 61:15–16, 73:2–6. Dr. Nercessian testified that, based on his training and clinical experience, he knew that cable breakage is "a known risk of any wire, any cable," *id.* at 102:11, as "[a]ny cable can break if you have enough force applied to it for a long period of time," *id.* at 91:11–12. *See also, e.g.*, *id.* 83:8–17, 89:19–20. Dr. Nercessian further specified why cable breakage is a risk: cables tend to break by "reaching and exceeding the maximum fatigue strength of the metal." *Id.* at 91:15–16. Moreover, when asked whether he understood "from [his] general understanding and education and experience that cables can fracture," Dr. Nercessian replied, "Absolutely." *Id.* at 107:16–21. Dr. Nercessian's testimony establishes that he was aware of the risk of cable breakage, and his independent knowledge constitutes an intervening event that relieves Defendants of any liability for failure to warn. *See, e.g.*, *Fane v. Zimmer, Inc.*, 927 F.2d 124, 126, 130 (2d Cir. 1991) (holding that an orthopedic surgeon was "fully aware" of the risk that a device implanted in the hip could break where the surgeon testified that the risk of breakage was "a known medical complication if the

bone does not heal"); *Prohaska*, 138 F. Supp. 2d at 445 (finding that an orthopedic surgeon was independently aware of the risk of breakage in surgical bone screws based on his deposition testimony that "parts of the instrumentation could break due to metal fatigue").

Plaintiffs nonetheless argue that Dr. Nercessian's knowledge of this risk is genuinely disputed for three reasons. First, as Plaintiffs accurately note, Dr. Nercessian testified that he had never seen cable breakage in a GTR device prior to Ms. Tomaselli's case. *See, e.g.*, Nercessian Dep. Tr. at 85:22–23, 88:11–15, 116:11–19. The fact that Dr. Nercessian had not previously encountered the adverse event that occurred in this case, however, does not demonstrate that Dr. Nercessian was not aware of the risk that this event might occur. *Cf. Fane*, 927 F.2d at 130 (holding that an orthopedic surgeon was sufficiently aware of the risk of breakage based on his testimony that he was "not surprised to learn of two instances of breakage"). Second, Plaintiffs point to Dr. Nercessian's testimony that he did not advise Ms. Tomaselli of the risk of cable breakage. *See* Nercessian Dep. Tr. at 37:6–8, 37:19–23. However, Dr. Nercessian's decision not to inform Ms. Tomaselli of this risk is not evidence that he did not know of the risk. *See, e.g.*, *Fane*, 927 F.2d at 126, 130 (holding that an orthopedic surgeon was independently aware of risks although he "did not know if he conveyed information about the risks" to the patient); *Ohuche*, 903 F. Supp. 2d at 147 (finding that the informed intermediary doctrine applied even though the treating physician "could not recall what she told [the patient] about the efficacy" of a vaccine before administering it); *Glucksman*, 553 N.Y.S.2d at 726 (applying the informed intermediary doctrine where the treating physician "testified that he was independently aware of the dangers involved" despite his "decision not to inform the plaintiff of the risk" of a side effect the patient ultimately experienced).

Finally, Plaintiffs argue that Dr. Nercessian's awareness of the risk of cable breakage is simply too general to demonstrate that he knew of the specific risk that cables may break in a GTR device. In particular, Plaintiffs point to Dr. Nercessian's statement that "any mechanical gadget has a fatigue life," and "[i]f you exceed that, it will give and break." Nercessian Dep. Tr. at 83:8–10. However, Dr. Nercessian made this statement when specifically asked to enumerate the "possible adverse effects associated with reattaching the greater trochanter." *Id.* at 82:11–14. Moreover, after Dr. Nercessian referenced "any mechanical gadget," he returned quickly to the subject of cable breakage in the context of surgical repairs to the greater trochanter, stating that "[t]he fatigue could persist after union occurs, and I've seen it numerous times with heal greater trochanter and the Ultron wires will break." *Id.* at 83:13–16. Read in context, Dr. Nercessian's reference to "any mechanical gadget" plainly served to illustrate the principle of cable breakage to a lay audience, not to indicate that he lacked any knowledge about that risk in the specific context of GTR devices.

More broadly, there can be no dispute that Dr. Nercessian's understanding of the risk of cable breakage derives from his training and experience as an orthopedic surgeon. For example, Dr. Nercessian testified that he learned about cable breakage "because we studied [it] in biomechanics" and because such breakage results from "fatigue strength," and "every orthopedic surgeon knows that." *Id.* at 94:23–95:12. Furthermore, Dr. Nercessian testified that "[i]f a patient live[s] long enough and has cable, of course it could break." *Id.* at 90:5–6. And when asked specifically whether a cable implanted to repair a greater trochanter fracture may break in the event of a non-union, Dr. Nercessian replied, "Definitely." *Id.* at 91:17–19. Plaintiffs have not pointed to any other testimony or evidence that could reasonably cast doubt on Dr. Nercessian's awareness of the risk that cables in GTR devices may break. Thus, there is no genuine dispute that Dr. Nercessian

was independently aware of the risk of the adverse event that Ms. Tomaselli experienced, and his awareness of this risk is an intervening event that relieves manufacturer and distributor Defendants of liability to Ms. Tomaselli for failure to warn.

In sum, the Court concludes that there is no genuine dispute of material fact precluding summary judgment to Defendants on Plaintiffs' failure-to-warn claim.

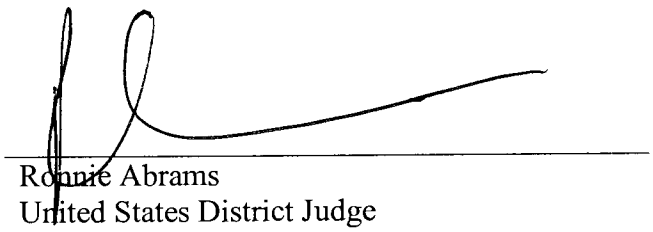
CONCLUSION

The Court has reviewed the remainder of the Report for clear error and, finding none, adopts Judge Netburn's thorough and well-reasoned Report in its entirety. Defendants' motion for summary judgment (Dkt. 103) is hereby granted, and Plaintiffs' counter-motion for summary judgment (Dkt. 118) is denied.

The Clerk of Court is directed to close this case. The Clerk of Court is further directed to change the caption of this action to remove the New York Presbyterian Hospital, the University Hospital of Columbia and Cornell, Columbia University College of Physicians and Surgeons, Columbia University Medical Center, and the Trustees of Columbia University in the City of New York as defendants.

SO ORDERED.

Dated: March 15, 2017
New York, New York



Ronnie Abrams
United States District Judge